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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,703	07/25/2001	Darrell R. Anderson	P 0280647	4927

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/911,703	ANDERSON ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 21-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 21-67 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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1. The previously pending species election requirement is withdrawn in view of applicants arguments.

2. Claims 21-67 are under consideration.

3. WO 94/11026 cited in the IDS filed 3/18/2004 was not considered because a copy of said reference has not received.

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The oath of the instant application claims priority to US applications 08/149099 and 08/149099 wherein said applications are not disclosed in the first sentence of the specification or an ADS.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 21-58,63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,736,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of antibody claims differ in scope (claim 1 is limited to "immunologically active chimeric anti-CD20" wherein the meaning of said term is as per disclosed in the specification and claim 1 is also limited in that the antibody is produced using a particular transfectoma which would influence certain characteristics of the antibody (such as glycosylation, etc)), the sequences recited in the antibody of claim 21 of the instant application are found in the antibody of claim 1 (the instant application is a continuation of the US application which yielded 5,736,137). Claims 2-5 disclose compositions containing the aformentioned antibody and a pharmaceutically acceptable carrier. The various radiolabels and chelator and dosages recited in the claims are obvious in view of the well established use of radiolabelled antibodies in the prior art. The antibody of claim 1 could be of any desire isotype depending on the particular use of the antibody. The particular dosages recited in the claims are encompassed by those recited in claims 4-6. Regarding claims 22-25, the antibody of claim 1 comprises the various sequences recited in the claims.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 21-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A) There is no support in the specification as originally filed for the chimeric antibody of claim 21-25. The specification discloses an "immunologically active" antibody with the limitations of claim 21 wherein the antibody has a single heavy and light chain. However, it does not disclose the scope of the claimed inventions which encompass antibodies which are not "immunologically active" (as per the definition of said tem in the specification page 13). It also does not disclose the scope of he claimed invention which encompasses antibodies with more than one heavy and light chain. Regarding applicants comments about the specification, pages 11-24, the scope of the claimed invention is not disclosed in the specification as originally filed for the aformentioned reasons.

B) There is no support in the specification as originally filed for the antibodies of claims 22-25. The chimeric chains of claims 22/23 encompass multichain antibodies. The specification discloses the C2B8 chimeric antibody which contains the heavy and light chains recited in claims 22-25. However there is no disclosure in the specification of chimeric antibodies which contain the heavy chain of claim 23/25 in combination with any light chain per se wherein the antibody has the functional properties recited in the claims. Similarly, there is no disclosure in the specification of chimeric antibodies which contain the light chain of claim 22/24 in combination with any heavy chain per se wherein the antibody has the functional properties recited in the claim. Regarding the specification, pages 11-24, there is no disclosure in said portion of the specification that the heavy or light chain variable regions of C2B8 would be expressed in combination with a different heavy or light chain variable region of nonC2B8 origin.

C) There is no support in the specification as originally filed for the claimed pharmaceutical compositions or imaging compositions. The terms "pharmaceutical composition" or "imaging composition" are not recited in the specification. The specification, page 14 discloses "immunologically active chimeric anti-CD20 antibodies

and radiolabelled anti-CD20 antibodies in a pharmaceutically acceptable buffer". However, clam 41 recites use of a "pharmaceutically acceptable carrier" wherein the term carrier is not disclosed in the specification. The carrier differs in scope from a buffer in that the carrier encompasses buffers and nonbuffers such as liposomes, etc. Furthermore, the pharmaceutical composition comprising encompasses other ingredients not disclosed in the specification such as additional active ingredients such as antibodies against antigens other than CD20, etc. Claim 42 recites use of a "acceptable carrier" wherein the term carrier is not disclosed in the specification. The carrier differs in scope from a buffer in that the carrier encompasses buffers and nonbuffers such as liposomes, etc. Furthermore, the imaging composition comprising encompasses other ingredients not disclosed in the specification such as additional active ingredients such as antibodies against antigens other than CD20, etc.
In addition, claims 43 and 44 encompass compositions with radiolabel that is not attached to the antibody recited in the claims and such compositions are not disclosed in the specification. The other limitations recited in the claims dependent on claims 41 and 42 are not disclosed in the specification in the context of the compositions of claims 41 and 42. There is also no support in the specification as originally filed for the dosages of clams 52 and 54. There is also no support in the specification as originally filed for the limitation recited in claim 57.

D) There is no disclosure in the specification as originally filed of the antibody of claim 58/59 or 63/64. Said antibody encompasses the recited variable region in combination with a nonhuman constant region (such as camel) or in combination with a constant region from a different mouse antibody (claims 59 or 64) wherein such antibodies are not disclosed in the specification as originally filed. Said antibodies also raise the issue of new matter because they encompass antibodies with a heavy or light chain other than that found in 2B8 and there is no disclosure of such antibodies in the specification as originally filed.

There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed inventions constitute new matter).

9. Regarding priority for the claimed inventions and the application of prior art, for the same reasons that the claimed inventions constitute new matter, they lack support in the various parent applications to which priority is claimed.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 21-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US Patent 5,736,137).

Anderson et al. teach the chimeric IgG1 antibody C2B8 (see columns 21-24) wherein the antibody has the variable light and heavy sequences recited in the claims (see figures and sequence listing). 2B8 is the murine antibody from which the variable regions of C2B8 was obtained wherein said antibody is encompassed by the antibody of claims 58,59,63,64 (see column 30). Anderson et al. teach 2B8 radiolabelled with yttrium-90 (see column 18). Anderson et al. teach yttrium-90 labeled C2B8 (see column 31). Anderson et al. use of the chelator MX-DPTA to radiolabel antibody with yttrium-90 or indium 111 (see column 7). Anderson et al. teach the aforementioned antibodies with a buffer (see column 8, first paragraph). Anderson et al. teach the intravenous administration of the aformentioned antibodies (see column 7, last paragraph) at a dosage encompassed by that recited in the claims (see column 8, second paragraph). Anderson et al. teach use of indium 111 radiolabelled antiCD20 antibody at a dosage encompassed by that recited in the claims (see column 9, penultimate paragraph).

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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